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Internal Management Procedure Title: **RESEARCH REQUEST APPLICATION PROCESS**		
Effective Date: November 15, 2004	**Revised**: May 1, 2006	**Authority :** NJ DOC PS # ADM.001.007
Promulgating Office: Administrative Policy & Procedure Manual Unit, Office of the Commissioner		**Professional Association Standard cited:**
Applicability: These procedures apply to all organizational units within the New Jersey Department of Corrections.		
Supersedes: N/A		
Review Schedule: This document is scheduled for annual review on or about May 1, 2007.		

Reviewed and Approved By: Douglas Gerardi, Director
Office of Policy and Planning

Doug Gerardi (Signature) 4/25/06 (Date)

Reviewed and Approved By: George W. Hayman, Acting Commissioner

(Signature) 5.4.06 (Date)

I. PURPOSE

To establish, set forth and maintain procedures for submittal and processing of a Form 980-1 *Research Request* to the NJ DOC Departmental Research Review Board (DRRB) whose duty is to review, initially approve or disapprove and certify requests to conduct academic research using subjects who are inmates of the NJ DOC or the records of inmates.

II. DEFINITIONS

The following words and terms, when used in this policy, shall have the following meanings, unless the context clearly indicates otherwise:

Assent means the agreement by an individual not competent to give legally valid informed consent (e.g. A child or cognitively impaired person) to participate in research.

Commissioner means the Commissioner of the New Jersey Department of Corrections, who is the Chief Executive Officer of the NJ DOC

Confidential or Confidential information means any information related to the NJ DOC official business or NJ DOC staff, determined by the NJ DOCs not to be disclosed by staff to unauthorized persons, entities or agencies to include media as defined in this policy. "Confidential" applies to any government record designated as confidential pursuant to the provisions of the Open Public Records Act at N.J.S.A. 47:1A-1 et seq. and any other record and/or information deemed confidential pursuant to any other state or federal laws or state regulations. Examples of "confidential" include, but are not limited to records and/or information relating to:

1. An individual, staff member, inmate, NJ DOC organizational unit or program which, if disclosed would jeopardize the safety of any person and/or the safe, secure and orderly operation of the correctional facility or other NJ DOC unit;
2. An informant document and/or statement;
3. A document pertaining to an individually identifiable crime victim(s) and/or family member(s) of a victim(s);
4. A comprehensive criminal history ("rap sheet");
5. A right of a staff member or inmate for which a reasonable expectation of privacy exists such as, but not limited to a medical, psychological, psychiatric, or treatment report, assessment, evaluation, summary, history, or recommendation;
6. Security issues regarding facility or plant design, staffing levels, scheduling, work and special assignments, deployment, and security related operating policies, procedures and post orders; and
7. Any disclosure of Departmental data that has the potential to negatively impact or threaten the safe, secure and orderly operation of the NJ DOC.

Departmental Research Review Board (DRRB) means the review panel representing the NJ DOC and the designated NJ DOC organizational unit where the research is requested to be performed. The DRRB ensures that research proposals are reviewed and, if approved, shall be conducted within the constraints of all organizational unit, NJ DOC, state and federal regulations, guidelines and requirements. At the completion of the DRRB review, the DRRB shall ensure that all recommendations to approve or disapprove research requests be presented to the Commissioner, NJ DOC for final review and determination of approval or disapproval prior to official notification to the requester. The DRRB shall be composed of the at least following members:

- Chairperson appointed by the Commissioner, NJ DOC from Central Office senior staff

- A member from the NJ DOC senior executive staff who has expertise, experience or general knowledge relative to the area of general research and/or the subject being researched;
- A member who shall be from the Office of the Ombudsman;
- A member who is the administrator or designee of the NJ DOC organizational unit housing the subject individual or population;
- A member who is the staff person designated as the organizational unit liaison for the project;
- Any other NJ DOC staff member deemed necessary of the DRRB Chairperson or the Commissioner or designee.

Human Subject(s)mean living individual(s) about whom a researcher conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy 45 CFR 46.102(f)].

Inmate means a person who has been convicted of a crime and sentenced to a correctional facility under the jurisdiction of the Commissioner of the NJ DOC.

New Jersey Department of Corrections or NJ DOC means that agency of the Executive Branch of the New Jersey State Government whose functions are to protect the public and provide for the custody, care, discipline, training and treatment of persons committed to the State correctional facilities.

Organizational Unit means a division, correctional facility or other work unit within the NJ DOC.

Research means a systematic investigation, including research development, testing and evaluation which may include, but not be limited to interviews, observation, review and evaluation of existing records and/or comparison of documents, designed to develop or contribute to a generalizable body of knowledge.

III. POLICY

The New Jersey Department of Corrections may permit academic research involving inmates or inmate records under the control of the NJ DOC in accordance with the guidelines established in NJ DOC Policy ADM.001.007 *NJ DOC Departmental Research Review Board*. All requests for academic research are presented to, reviewed and certified by a Departmental Research Review Board (DRRB) on approved NJ DOC forms. Upon completion of the review of the research request, the DRRB shall recommend to the Commissioner, NJ DOC that the research be approved/disapproved. The Commissioner may then approve/disapprove the requested research be conducted in accordance with the provisions of this policy and all applicable internal management procedures. Without review by and recommendation of the DRRB and formal approval of the Commissioner, NJ DOC, no research may be pursued.

IV. PROCEDURES

NJ DOC Form 980-I is to be used for requesting DRRB review of any new research project. DRRB approval is required before any research involving human subjects, review of databases, files or records may be initiated.

A. PROCEDURE TO REQUEST DRRB REVIEW:

To request DRRB review, 5 copies (1 original and 4 copies) of each of the following items must be submitted to the DRRB, assembled in the following order:

a. Form 980-1 (available through the Office of Policy and Planning.)

b. Appendix A, "Researcher and Reviewer Checklist". This checklist is designed to assist the researcher in ensuring the completeness of the DRRB Protocol Form. It must be filled out *completely* and submitted with the application (i.e. "X" or "NA" for each item).

c. Attachment 1 - A complete copy of the research proposal, plan or protocol, that sets forth the objectives of the research and describes the procedures designed to reach that objective,

OR

A copy of the proposal or plan for a dissertation leading to an advanced degree.

d. Five copies of each of the following items must also be submitted, IF APPLICABLE to the proposal, labeled and attached in the following order:

- **Attachment 2** - Information for additional key personnel, if more than five individuals are involved.
- **Attachment 3** - All recruitment material, which must include a contact name, a brief description of the research and inclusion criteria.
- **Attachment 4** - The informed consent form that the subjects will sign and that can be used to document their informed consent.
- **Attachment 5** - Authorization letters from research sites that are not affiliated with NJ DOC (e.g. schools).
- **Attachment 6** - All questionnaires, surveys, interview schedules, tests, and any other test instruments proposed to be used, and Attachment 8 - focus group guides.

- **Attachment 7** - The debriefing statement that will be used if deception is involved in the study.

- **Attachment 8** - Authorization to use data if it is not publicly available.

- **Attachment 9** - Letters of collaboration and DRRB approval notices from institutions or organizations other than NJ DOC that are participating in the research.

B. THE BASIC DRRB REVIEW CRITERIA:

In order to approve research, the DRRB shall determine whether all of the following requirements have been satisfied, as applicable:

1. Risks to subjects are minimized, a) by using procedures that are consistent with sound research design and that do not unnecessarily expose the subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable, and the special problems of research involving vulnerable populations are adequately addressed.

4. Informed consent will be sought from each prospective subject.

5. Informed consent will be appropriately documented.

6. The research plan makes adequate provision for monitoring the data to ensure the safety of the subjects.

7. Adequate provisions are made to protect the privacy of the subjects and to maintain the confidentiality of data.

8. Appropriate additional safeguards have been included in the research plan when some or all of the subject inmates are likely to be vulnerable to coercion or undue influence.

9. The purpose of the research is consistent with the environmental setting in which it will be conducted.

C. THE INFORMED CONSENT FORM -- BASIC ELEMENTS:

The following information is to be provided to each subject in the informed consent form:

1. A statement that the study involves research, an explanation (in non-technical language) of the purposes of the research, a description of the procedures to be followed, and identification of any procedures that are experimental.

2. A description of any reasonably foreseeable *risks* or discomforts to the subject.

3. A description of any *benefits* to the subjects or other persons, that may reasonably be expected to result from the research.

4. A disclosure of appropriate alternative procedures or treatments that might be beneficial to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

   Cautionary Note: Even research records that are obtained via a "confidential" protocol may be subject to subpoena. If the researcher and/or the DRRB deem(s) it necessary to prevent the possibility of such compelled disclosure of the research records (e.g. in the case of potential revelation of criminal activity), the researcher may, in advance of initiating the research, apply to any of several government agencies (e.g. NIH) for a "Certificate of Confidentiality," which legally prevents any governmental agency from obtaining the researcher's records. Contact the Sponsored Programs Administrator for instructions on how to apply for this document.

6. A statement specifying the amount of time required for participation in the study (e.g. a *realistic* estimate of the number of minutes required to complete a questionnaire, the number of separate sessions, the overall duration [days, weeks, months] that the subject will be involved in the study).

7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation *at any time* without penalty or loss of benefits to which the subject is otherwise entitled. Specify the consequences, if any, to the subject of his/her decision to withdraw from the research before completing the protocol and procedures for orderly termination of participation by the subject (e.g. exit interview).

8. The following statement regarding subjects' rights: *"If you have any questions about your rights as a research subject, you may contact the Director, Office of Policy and Planning at NJ DOC at (609) 984-4578".*

ADDITIONAL ELEMENTS OF INFORMED CONSENT:

When appropriate, one or more of the following elements of information should be provided to each subject:

9. Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent.

10. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

11. The approximate number of subjects involved in the study.

FORMAT OF THE INFORMED CONSENT FORM:

1 Text should be written in non-technical terms, at a sixth-grade reading level, with non-technical explanation of any specialized terms. If the consent form is more than one page, include a notation, "Subject's Initials _____", at the bottom of each page except the signature page.

2 If non-English speaking subjects will be involved, a consent form that has been translated into the relevant language is required.

3 Signature lines for the Principal Researcher and the subject, with corresponding lines for the date of each signature, are required. Signature lines for a legally authorized representative or minor subject may also be necessary, depending upon the categories of subjects that are involved. A witness signature is not required in most cases; exceptions are oral consent verification (below) and situations in which a legally authorized representative signs for the subject.

4 If the protocol involves videotaping, audio-taping, or photographing of subjects, the consent form must include either a separate statement of agreement for these procedures within the consent document, with signature line, or an addendum to the consent form describing the recording procedure with a statement of agreement and signature line. The purpose of the distinct signature for these procedures is to ensure that the subject is aware of their inclusion, and if the study design permits, to allow the subject to participate in the study without being recorded.

Provide either:

a) a detailed written form that incorporates the elements of informed consent,
OR
b) a brief written document stating that the elements of informed consent will be presented orally to the subject or the subject's legally authorized

representative and witnessed by a third party. In either case, a copy of the document should be given to the person signing the form.

5. A written summary of the oral presentation should be included in your Request for Review.

D. THE THREE CATEGORIES OF DRRB REVIEW:

Based on the criteria provided below, researchers should request, on the DRRB application and on the checklist provided, one of the following types of review: 1) full DRRB panel review, or 2) expedited DRRB review.

1. FULL DRRB PANEL REVIEW:

All proposals that do not qualify for expedited review shall be reviewed by the full DRRB Panel.

2. EXPEDITED REVIEW:

Specific research areas that qualify for expedited review:

a. Research involving materials [data, documents, records, or specimens] that have been collected or will be collected solely for non-research purposes, such as medical treatment or diagnosis.

b. Collection of data from voice, video, digital, or image recordings made for research purposes.

c. Research on individual or group characteristics or behavior [including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior] or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

d. Continuing review of research previously approved by the convened DRRB as follows where:

- the research is permanently closed to the enrollment of new subjects;
- all subjects have completed all research-related interventions; and
- the research remains active only for long-term follow-up of subjects; OR
- where no subjects have been enrolled and no additional risks have been identified; OR
- where the remaining research activities are limited to data analysis.

e. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

f. Research and demonstration projects which are conducted by or subject to the approval of Federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

E. REVISIONS AFTER DRRB REVIEW

If the research requestor submits a revised protocol following recommendations in the DRRB review, any revisions, must be indicated in the margins. Colored highlighting pens are NOT to be used, because the highlighting either does not show up, or it obscures the text in photocopies. In addition, the research requestor must submit an entire "clean" copy of the revised version that is devoid of the markings that identify the revisions.

F. MISCELLANY

1. Continuing review:

Continuing review by the DRRB is required at least annually. Approximately two months before the expiration date of the protocol, the DRRB office will mail a form entitled *Request for Continuing Review* to principal researchers, which must be completed and returned promptly. If the form is not returned by the end of the approval period, the protocol will be administratively inactivated, in which case the research must be terminated immediately.

2. Change in protocol or principal researcher:

Whenever an ongoing project acquires a new principal researcher, or whenever there is a change in the protocol or the subject population, the DRRB must be notified in writing. Upon approval of the modification, the DRRB will issue a revised notice of approval.

3. Adverse Events:

All adverse and/or unexpected events experienced by participants in research studies must be reported immediately to the DRRB.

4. Federal grant applications:

   If the project is being submitted to a Federal agency that requires DRRB review, the DRRB must be advised of this fact and also be provided the address of the person in The Federal agency who is to be notified once the project has received DRRB approval.

5. Assistance in completing the request form:

   For further information, and for discussion of problems arising in particular studies, please call Office of Policy and Planning at (609) 984-4578.

6. DRRB decisions:

   All DRRB decisions will be communicated to researchers in writing. On occasion, a researcher may be invited to appear before the DRRB to provide information about matters not covered in the request for review. In the unlikely event of an unresolvable conflict between the DRRB and a researcher, the case will be referred to the Commissioner of the NJ DOC for further review.

G. SUBMISSION DATES

The DRRB meets monthly and all Requests for Review must be received in the DRRB office by the 10th of the month in order to be considered at the next-scheduled meeting (e.g. received by January 10th for review at the February meeting). Requests received later than the 10th will be held until the subsequent month's meeting (e.g. received on January 11th for review at the March meeting).

INQUIRIES AND SUBMISSIONS SHOULD BE DIRECTED TO:

Director Office of Policy and Planning
New Jersey Department of Corrections
P.O. Box 863
Trenton, NJ 08625-0863

V. CROSS REFERENCE DOCUMENTS AND DOCPS/IMP

DOCPS/IMP/Document Number	Title	Effective/Revision Date
ADM.001.007	*New Jersey Department of Corrections Departmental Research Review Board (DRRB)*	January 10, 2006
45 CFR - 46	*Code of Federal Regulations TITLE 45 PART 46 PROTECTION OF HUMAN SUBJECTS*	November 13, 2001

VI. APPLICABLE FORMS

Form Number	Form Title	Effective/ Revision Date
980-I	*Research Request*	Rev. November 10, 2004
	Request for Continuing Review	Pending